

Site Performance Markers
PM-TESMC/01/02

| Call Center | 16-Sep-02 | 23-Sep-02 | 30-Sep-02 | 7-Oct-02 | | | | |
|---|----------------|---------------------|----------------|---------------------|----------|---------------------|----------|----------|
| No. Subjects Screened (telephone) | 141 | 170 | 180 | 281 | | | | |
| No. Subjects Scheduled | 5 | 14 | 20 | 47 | | | | |
| No. Subjects Completed | 74 | 78 | 78 | 87 | | | | |
| No. Subjects Removed | 1 ^a | 1 ^a | 1 ^a | 1 ^a | | | | |
| No. of Subjects Completed and Evaluable | 73 | 77 | 77 | 86 | | | | |
| | | | | | | | | |
| Site Activity | | | | | | | | |
| No. of Active Sites | 1 | 1 | 1 | 3 | | | | |
| No. of Inactive Sites | 40 | 40 | 40 | 38 | | | | |
| No. Sites with Low Enrollment (< 10 subjects/4 weeks) | 0 | 0 | 0 | 0 | | | | |
| | | | | | | | | |
| Status of Samples | Received | Analyzed | Received | Analyzed | Received | Analyzed | Received | Analyzed |
| No. of Samples Received/Analyzed by Harrogate | | | | | | | | |
| Nicotine and Metabolites | 55 | 0 | 55 | 0 | 55 | 0 | 55 | 0 |
| 4-ABP | 55 | 0 | 55 | 0 | 55 | 0 | 55 | 0 |
| 11-dehydro-thromboxane B2 | 55 | 0 | 55 | 0 | 55 | 0 | 55 | 0 |
| 8-epi-prostaglandin F2alpha | 55 | 0 | 55 | 0 | 55 | 0 | 55 | 0 |
| No. of Samples Received/Analyzed by MDS | | | | | | | | |
| Total Antioxidant Capacity | 47 | 0 | 61 | 0 | 78 | 0 | 78 | 0 |
| NNAL | 47 | 0 | 55 | 0 | 55 | 0 | 78 | 0 |
| 3-HPMA | 47 | 0 | 56 | 0 | 56 | 0 | 78 | 0 |
| 1-,3-Butadiene | 47 | 0 | 56 | 0 | 56 | 0 | 56 | 0 |
| Polycyclic Aromatic Hydrocarbons | 47 | 0 | 61 | 0 | 61 | 0 | 61 | 0 |
| No. of Samples Received/Analyzed by MDS | | | | | | | | |
| Cigarette Filters | 18 | 0 | 18 | 0 | 18 | 0 | 18 | 0 |
| No. of Subjects Consented for Sample Banking | 48 | 53 ^c | | 53 ^c | | 54 ^c | | |
| No. of Subjects with Missing, Broken, Hemolytic samples, etc. | 1 | 1 | | 1 | | 1 | | |
| | | | | | | | | |
| Status of Data | | | | | | | | |
| No. of CRFs Frozen | 0 | 0 | | 0 | | 0 | | |
| No. of Questionnaires Scanned | 4 | 4 | | 77 | | 77 | | |
| No. of Topography Downloads/No. of Smokers | 45/45 | 48 ^d /49 | | 48 ^d /49 | | 57 ^d /58 | | |
| No. of Subject Files Transferred to MDS Data Management | 0 | 0 | | 0 | | 0 | | |

a #15 removed (Site 1), did not qualify for study

b #30 (site 1), #80 (site 4), #47 and #70 (site 5), #36 (site 7), #43 (site 32), #29, #52 (Site 35), removed, tar level for cigarette brand not known

c 54 consented, 52 collected; #70 and #79 consented but were difficult to draw so no sample collected for banking

d Data for #72 missing

1/27/2003

Site Performance Markers
PM-TESMC/01/02

| Call Center | 14-Oct-02 | 28-Oct-02 | 4-Nov-02 | 11-Nov-02 |
|---|---------------------|------------------|-----------------|------------------|
| No. Subjects Screened (telephone) | 617 | 2376 | 3951 | 4927 |
| No. Subjects Scheduled | 250 | 533 | 515 | 488 |
| No. Subjects Completed | 117 | 354 | 635 | 924 |
| No. Subjects Removed | 1 ^a | 2 ^b | 6 ^b | 5 ^{a,b} |
| No. of Subjects Completed and Evaluable | 116 | 352 | 629 | 919 |
| Site Activity | | | | |
| No. of Active Sites | 14 | 15 | 23 | 23 |
| No. of Inactive Sites | 27 | 26 | 18 | 18 |
| No. Sites with Low Enrollment (< 10 subjects/4 weeks) | 0 | 0 | 0 | 0 |
| Status of Samples | | | | |
| | Received | Analyzed | Received | Analyzed |
| No. of Samples Received/Analyzed by Harrogate | | | | |
| Nicotine and Metabolites | 55 | 0 | 200 | 0 |
| 4-ABP | 55 | 0 | 108 | 0 |
| 11-dehydro-thromboxane B2 | 55 | 0 | 55 | 0 |
| 8-epi-prostaglandin F2alpha | 55 | 0 | 55 | 0 |
| No. of Samples Received/Analyzed by MDS | | | | |
| Total Antioxidant Capacity | 78 | 0 | 113 | 0 |
| NNAL | 78 | 0 | 78 | 0 |
| 3-HPMA | 78 | 0 | 78 | 0 |
| 1-,3-Butadiene | 56 | 0 | 78 | 0 |
| Polycyclic Aromatic Hydrocarbons | 61 | 0 | 106 | 0 |
| No. of Samples Received/Analyzed by MDS | | | | |
| Cigarette Filters | 18 | 0 | 79 | 0 |
| No. of Subjects Consented for Sample Banking | 59 ^c | etials | etials | etials |
| No. of Subjects with Missing, Broken, Hemolytic samples, etc. | 6 | CCLS | 66 | 235 |
| Status of Data | | | | |
| No. of CRFs Frozen | To be discussed | etials | etials | etials |
| No. of Questionnaires Scanned | 96 | 96 | 96 | 188 |
| No. of Topography Downloads/No. of Smokers | 65 ^d /66 | etials | etials | etials |
| No. of Subject Files Transferred to MDS Data Management | 0 | 0 | 0 | 0 |

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b #30 (site 1), #80 (site 4), #47 and #70 (site 5), #36 (site 7), #43 (site 32), #29, #52 (Site 35), removed, tar level for cigarette brand not known

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| | | | | | | | | |
|---|------------------|----------|-----------------|----------|-----------------|----|----------|--|
| Call Center | 18-Nov-02 | | 25-Nov-02 | | 2-Dec-02 | | 9-Dec-02 | |
| No. Subjects Screened (telephone) | 7046 | | 8357 | | 8837 | | | |
| No. Subjects Scheduled | 872 | | 830 | | 768 | | | |
| No. Subjects Completed | 1144 | | 1263 | | 1311 | | | |
| No. Subjects Removed | 5 ^{a,b} | | 9 ^{ab} | | 9 ^{ab} | | | |
| No. of Subjects Completed and Evaluable | 1139 | | 1254 | | 1302 | | | |
| | | | | | | | | |
| Site Activity | | | | | | | | |
| No. of Active Sites | 31 | | 33 | | 35 | | | |
| No. of Inactive Sites | 10 | | 8 | | 6 | | | |
| No. Sites with Low Enrollment (< 10 subjects/4 weeks) | 0 | | 0 | | 0 | | | |
| | | | | | | | | |
| Status of Samples | Received | Analyzed | Received | Analyzed | | | | |
| No. of Samples Received/Analyzed by Harrogate | | | | | | | | |
| Nicotine and Metabolites | 200 | 0 | 200 | 0 | 200 | 0 | | |
| 4-ABP | 108 | 0 | 403 | 0 | 403 | 0 | | |
| 11-dehydro-thromboxane B2 | 223 | 55 | 223 | 55 | 223 | 55 | | |
| 8-epi-prostaglandin F2alpha | 229 | 55 | 229 | 55 | 229 | 55 | | |
| No. of Samples Received/Analyzed by MDS | | | | | | | | |
| Total Antioxidant Capacity | 113 | 0 | 472 | 0 | 472 | 0 | | |
| NNAL | 202 | 0 | 202 | 0 | 202 | 0 | | |
| 3-HPMA | 232 | 0 | 232 | 0 | 232 | 0 | | |
| 1-,3-Butadiene | 375 | 0 | 375 | 0 | 375 | 0 | | |
| Polycyclic Aromatic Hydrocarbons | 106 | 0 | 490 | 0 | 490 | 0 | | |
| No. of Samples Received/Analyzed by MDS | | | | | | | | |
| Cigarette Filters | 143 | 0 | 143 | 0 | 143 | 0 | | |
| No. of Subjects Consented for Sample Banking | etrials | | etrials | | 645 | | | |
| No. of Subjects with Missing, Broken, Hemolytic samples, etc. | 244 | | 255 | | 250 | | | |
| | | | | | | | | |
| Status of Data | | | | | | | | |
| No. of CRFs Frozen | etrials | | etrials | | 131 | | | |
| No. of Questionnaires Scanned | 472 | | 472 | | 925 | | | |
| No. of Topography Downloads/No. of Smokers | etrials | | etrials | | etrials | | | |
| No. of Subject Files Transferred to MDS Data Management | 0 | | 0 | | 0 | | | |

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